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WILLIAM J. MCNICHOL, JR., ESQ.
REED SMITH LLP
2500 One Liberty Place
1650 Market Street
Philadelphia, PA 19103

EXAMINER	
KIM, VICKIE Y	

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/864,083
Filing Date: May 23, 2001
Appellant(s): MITCHELL S. WORTZMAN

Maryellen Feehery
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed August 20, 2004.

(1) Real Party in Interest

A statement identifying the real party in interest, Medicis Pharmaceutical Corp. ("Appellant"), is contained in the brief.

(2) Related Appeals and Interferences

RP

The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. Therefore, it is presumed that there are none. The Board, however, may exercise its discretion to require an explicit statement as to the existence of any related appeals and interferences.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of claims contained in the brief is correct in noting that no amendment filed subsequent to the final rejection.

(5) Summary of Invention

The summary of invention contained in the brief is correct. The invention relates to a composition comprising hydroquinone, and a cationic salt of acidic ascorbyl esters. Invention also recites the said composition's pH of about 5.5 to about 8.0. The dependent claims further recites inorganic salts such as magnesium ascorbyl phosphate as the cationic salt of acidic ascorbyl esters, aminopropyl ascorbyl phosphate, and sodium metabisulfite as antioxidant.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The appellant's statement regarding grouping of claims in the brief is correct.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5,932,612	***Gordon***	***8/3/1999***
5,980,871	***Lukenbach***	***11/9/1999***

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-23 are rejected under 35 U.S.C. 103(a).

This rejection is summarized as follows:

1. Claims 1-23 are rejected under 35 U.S.C. 103(a) as being obvious over Gordon (US 5932612) alone.

First, The claims 1-8 and 14-18 are drawn to a composition comprising hydroquinone(1-12%) and magnesium ascorbyl phosphate(0.1-3%) wherein the pH of composition is about 5.5 to 8.

Gordon (US'612, hereinafter) teaches a skin lightening composition used in the treatment of hyperpigmentation, wherein said composition comprising a derivative of ascorbic acid such as magnesium ascorbyl phosphate, hydroquinone. US'612 further teaches that a derivative of ascorbic acid(e.g. magnesium ascorbyl phosphate) is present in an amount of about 0.05%-10%(see claims 13-17), and hydroquinone present in an amount about 1.5-4% (see claims 1 & col. 2, lines 66-67).

Although Gordon does not explicitly mention about pH of the patented composition, it would have been readily apparent to the one of ordinary skill in the art that the final product would have had similar environment (e.g. 5.5-8) because the said ingredient would have been most stable so that similar pH would have been an ideal condition for the product using the same ingredient. It is again noted that, all the critical elements required by the instant claims are well taught and the structure of claims are met. Furthermore, the techniques and skills are well within the skill level of any artisan having ordinary skill in the art and thus, obvious over the Gordon reference teaching, absent evidence to the contrary.

One would have been motivated to make such modification because it is conventionally well known that the ideal cosmetic/dermatological product should be stable and have final pH near physiological pH(about 7) since skin irritation would have been minimized when the pH of the composition is near physiological pH. The said concern is well recognized by the patentee(Gordon), for example, Gordon's concern is directed to the reduction of the skin irritation during the treatment, see abstract.

Second, as to the limitations recited in dependent claims 11-13 and 19-23(i.e. sodium metabisulfite and aminopropyl ascorbyl phosphate or sodium ascorbyl phosphate), Gordon (US'612) teaches sodium bisulfite(comparable to sod. metabisulfite) and ascorbic acid derivatives such as ascorbyl palmitate, magnesium ascorbyl phosphate or ascorbyl linoleate where all the said derivatives are old and well known* (utilized) in the art where one would have been motivated to make such substitution, with reasonable expectation of success, because they share very same

chemical structures and pharma-cores(that is responsible for the therapeutic effects) and similar physical properties, absent evidence to the contrary(*see extrinsic supporting documents enclosed in PTO-892).

Claims 1-9 are rejected under 35 USC 103(a) as being unpatentable over Lukenbach et al(US5980871) in view of Gordon (US5932612).

Lukenbach et al(US'871) teach two examples wherein each separate skin composition using magnesium ascorbyl phosphate (3%) or hydroquinone(2%) as an active skin whitening agent(depigmentation agent) and the pH of each composition is adjusted to 7.5, see example 100b and 100c at col. 16 and col.6, lines 66-67. US'871 also teaches use of sulfate and sodium sulfate incorporated into the said examples.

Applicant's claims differ in that they require both depigmentation agents together in one final product. Applicant's claims 11-13 require sodium metabisulfite.

As mentioned above in 103 rejection, Gordon remedies the deficiencies of Lukenbach's patent because Gordon teaches the combination of mag. ascorbyl phosphate and hydroquinone. Furthermore, Gordon teaches sod. bisulfite in his skin whitening composition.

Thus, it would have been obvious to one of ordinary skill in the art at that time of the invention was made to employ both depigmentation agents together because the combination of active ingredients having same activities are conventionally used to increase the effectiveness.

One would have been motivated to make such modification because the combination of active ingredient with same character would have maximized therapeutic

efficacy by reducing side effects including skin irritation by lowering the dose of each active agent used in the treatment while the outcome is substantially same or better.

When these two references are taken together, one would have been motivated to make the combination of hydroquinone and magnesium ascorbyl phosphate where stability of each ingredients at pH=7.5 (as shown in Luckenbach) and also in combination form (as proven in Gordon's),with reasonable expectation of success.

(11) Response to Argument

Appellants' argument filed Aug.20, 2004 have been fully considered but they are nor persuasive. Thus, art rejection of the record is maintained and all the claims are properly included in the said rejection.

Appellents argue that Gordon and Lukenbach in view of Gordon fail to establish a prima facie case of obviousness because each patentee does not teach or suggest all and each claim limitations of claim 1, and thus, Gordon or Lukenbach in view of Gordon does not render obvious claims

Gordon

Skin irritation is considered to be primary concern in dermatological/cosmetic/ pharmaceutical industry since skin irritation often become a major reason for the drawback or responsible for unsatisfactory outcome or failure .

As Gordon(US'612) acknowledges in his patent , the patentee's concern is directed to the reduction of skin irritation during hyperpigmentation treatment, see

abstract. It is conventional known to the ordinary skilled artisan that either too high(basic) or too low(acidic) product directly triggers unwanted skin irritation, where the physiological pH(about pH=7) is often considered to be an ideal pH for final products.

Appellent's argument that hydroquinone(e.g. 4% or less) is instable in environment having pH above 4, however, the allegation of appellent is not persuasive because at the time of the invention was made it is conventional wisdom that the stable hydroquinone or magnesium ascorbyl phosphate containing composition can be formulated by adjusting pH to about 7.5 . For supporting the examiner's allegation, for instance, Lukenbach(US5980871) patent teaches, "...salts of fatty acids are used care should be taken to keep the pH above..... In retaining stability and efficacy of the composition", see col. 6, lines 46-54. It would have been readily apparent that patentee concerns stability and efficacy of the patented composition where patentee adjusts pH before storing the product if necessary to ensure stability.

It would have been apparent to any skill in the art that Gordon's concern (i.e. reduction of skin irritation) would have been resolved by adjusting the pH of final product is near physiological pH(about 7). Although Gordon does not explicitly mention about pH, one of ordinary skill in the art would concluded that Gordon's patented composition is physiological pH compatible(near 7), or adjusted to near pH=7. Modifying pH of hydroquinone or ascobyl phosphate is considered to be a minor variation, that is conventional and routinely practiced.(see extrinsic supp. Document such as Lukenbach).

In any event, Appellents fail to distinguish the instant claims from the cited reference. Broad description of claimed subject matter(i.e. a composition comprising two structural components as critical elements are easily met by a combination of hydroquinone and a ascorbic acid esters such as magnesium ascorbyl phosphate(Gordon's) and the pH does not render the claimed invention patentably distinct over the prior art of the record for the reasons of record.

As mentioned earlier, pH modification or substitution with functionally equivalent species (e.g. sod. bisulfite vs sod. metabisulfite; or magnesium ascorbyl phosphate vs sodium ascorbyl phosphate or aminopropyl ascorbyl phosphate) are considered to be minor variation which does not render the claims patentable. The said minor variations are routinely practiced in the industry to determine most effective results(skin whitening activity).

Thus, the 103 rejection over Gordon should be maintained and the claims should be maintained as rejected.

Lukenbach in view of Gordon

Hydroquinone and a cationic salt of acidic ascorbyl esters(i.e. magnesium ascorbyl phosphate) are proven to be effective as depigmentation agent which is effectively used in both patents.

The deficiency of Lukenbach from instant claims (i.e. the combination of hydroquinone and mag. Ascorbyl phosphate is not explicitly exemplified) is remedied when Gordon's combination is taken together(Lukenbach in view of Gordon), since

each ingredients are effective depigmentation agent and stable in pH about 7.5, one would have been reasonably expected successful outcome when these are combined.

The combination of active ingredient with the same character is merely the additive effect of each individual component, See *In re Kerkhoven*, 205 USPQ 1069(CCPA 1980)

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

VICKIE KIM
PRIMARY EXAMINER

Vickie Kim
Primary Patent examiner
Art unit 1618

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

(conferee)

THURMAN K. PAGE, M.A., J.D.
SUPERVISORY PATENT EXAMINER